



Decide with Confidence

SPL Release Four Training Session: Preparing Electronic Drug Registration and Drug Listing Submissions Session Three (Face-to-Face)

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Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing¹

DRAFT GUIDANCE, July 2008

Page 10

c. Site-specific D-U-N-S[®] Number

FDA recommends that the D-U-N-S[®] Number (as described in section V.B.2 of this document) should be submitted for each site-specific entity (e.g., the registrant, establishments, U.S. agent, importer). Submitting the site-specific D-U-N-S[®] Number for an entity would provide by reference to the number certain business information for that entity, e.g., trade names used by the entity, addresses, additional ownership information, such as the name of each partner or the name of each corporate officer and director, and the state of incorporation otherwise required for drug establishment registration.

¹ See [http://www.fda.gov/cder/guidance/OC2008145\(2\).pdf](http://www.fda.gov/cder/guidance/OC2008145(2).pdf) for additional information

D&B Overview



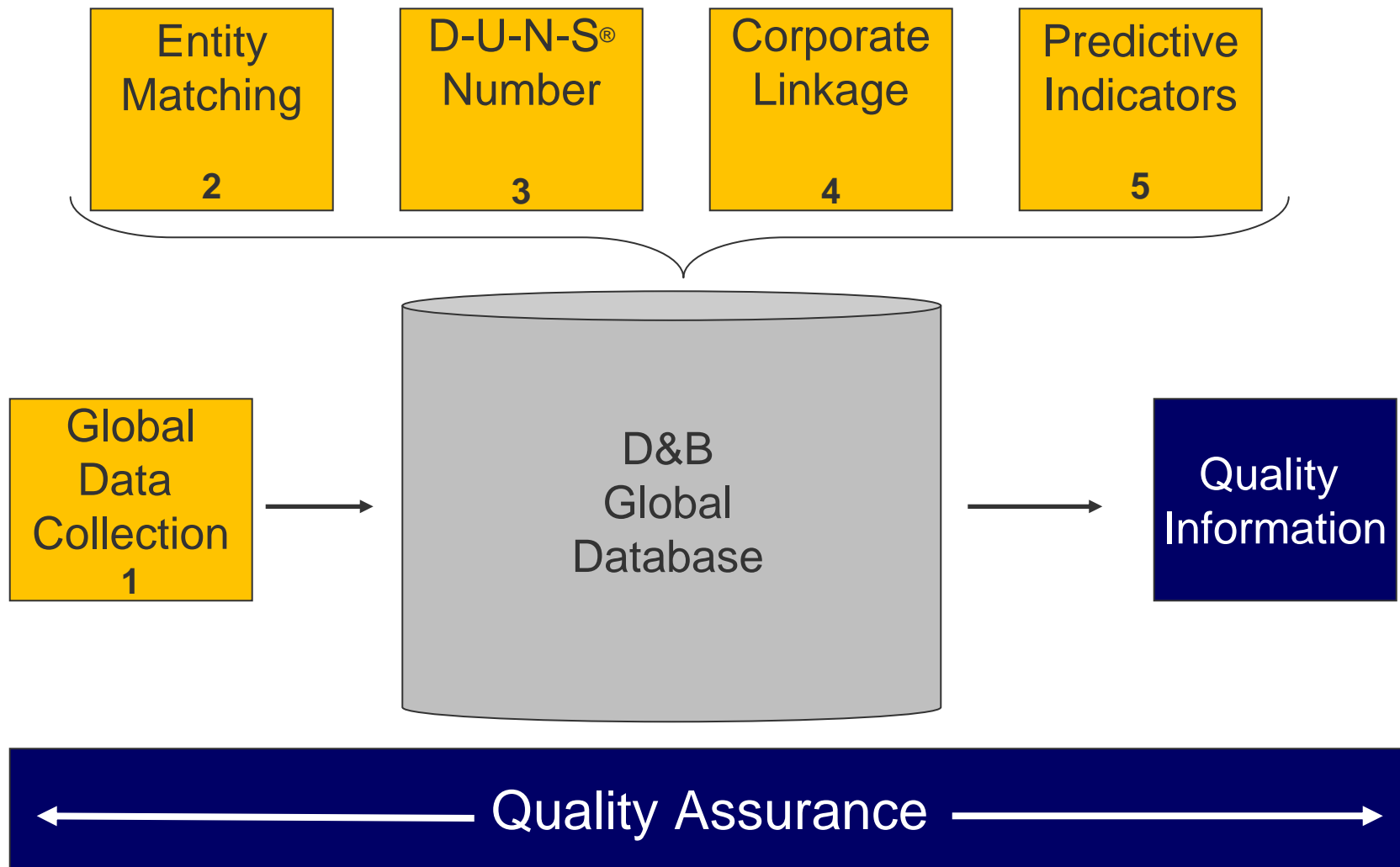
Decide with Confidence

- D&B is a global organization
 - Business information coverage in over 190 countries
 - 37 offices around the world with 5,300 employees
- 167 years of experience - collecting, cleansing, and enriching data
- DUNSRight™ data quality process
- \$260M invested each year on data quality, collection, and maintenance
- 40 years of experience maintaining the D-U-N-S® Number
- Thousands of global data sources
 - Accounts payable experiences, court & legal filings, financial statements, government registries, news & media, yellow pages, direct investigations
- D&B helps our clients “Decide with Confidence”
 - 250,000 customers worldwide
 - Over 90% of the Business Week Global 1000
 - All federal government departments and most agencies

DUNSRightTM assures quality business information



Decide with Confidence



The foundation of our solutions is robust, accurate, and timely information



Decide with Confidence

Direct Investigations

Payment Data

Government Registries

U.S. Public Records

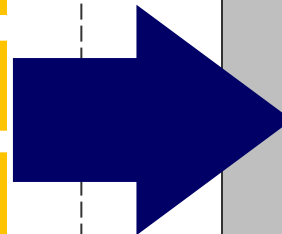
Company Financial Information

Courts & Legal Filings

Telephone Directories

Web Sources

News and Media



D&B Global Database

146 Million Businesses

- Over 190 countries
- 9.6 million linked records
- \$260 million spent annually
- Data quality/maintenance

Over 1.5 Million Updates Daily

The D-U-N-S® number provides both a widely adopted standard and unique set of capabilities



Data-Universal-Numbering-System

A unique nine-digit global business identification system that identifies, validates and relates more than 146 million businesses worldwide

The value D&B brings is not just its number—it is in the system we have developed for maintaining accurate, comprehensive, and timely entity information.

This system, consisting of data acquisition, standardization, matching, distribution, and quality assurance is *the* critical component in business identification.

The number is the easy part...the system is the challenge.

**D-U-N-S® Number recognized by over
50 governments and international trade
associations**



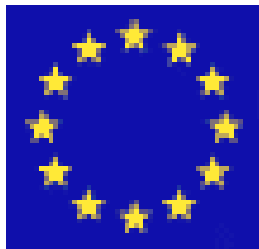
Decide with Confidence



**The United
Nations**



**International
Standards
Organization**



**European
Commission**



**US Government
– OMB Mandate**



**Australian
Government**

Obtaining a D-U-N-S® Number



1. Free Service:

- http://www.dnb.gov.com/federal_compliance/fda/DUNSrequest/requestGuide.html
- Available to support requests for D-U-N-S® Numbers for your establishments; D-U-N-S® Numbers request for your U.S. agents, importers, suppliers is not available through the no-fee service
- U.S. entity requests take up to 20 business days to complete / non-U.S. entity requests take up to 40 business days

2. Expedited D-U-N-S Request Service: **Recommended**

- <http://www.dnb.com/dunsrequest>
- \$14.95 for each D-U-N-S® Number requested
- Requests can be made for D-U-N-S® Numbers on your establishments, as well as your U.S. agents, importers, and suppliers
- U.S. entity requests take up to 10 business days to complete / non-U.S. entity requests 20 business days
- Dedicated fulfillment staff for tracking requests

3. Through an existing contract your business may currently have with D&B:

- Contact your D&B Relationship Manager for service availability and options